

## Notice of Allowability

Application No.

09/909,796

Examiner

J. D. Schultz, Ph.D.

Applicant(s)

TAYLOR ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of May 25, 2004.
2. ☒ The allowed claim(s) is/are 1 and 87-89.
3. ☒ The drawings filed on 12 November 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Teresa Lavenue on August 3, 2004.

The application has been amended as follows:

Claim 1 (currently amended): A method for inhibiting or delaying apoptosis in vitro in a cell or cells of a mammalian corpus luteum, comprising administering to said cell or cells an agent that is capable of inhibiting an apoptosis-induced DHS catalyzed chemical reaction, wherein the agent is selected from the group consisting of spermidine, 1,3-Diamino-propane, 1,4-Diamino-butane (putrescine), 1,7-Diamino-heptane, and 1,8-Diamino-octane;

and wherein said inhibiting apoptosis-induced DHS catalyzed chemical reaction reduces levels of activated apoptosis-induced eIF-5A or inhibits activation of apoptosis-induced eIF-5A; and wherein said reduction of apoptosis-induced eIF-5A or inhibition of activation of apoptosis-induced eIF-5A inhibits or delays apoptosis.

Claim 87 (currently amended): A method for inhibiting or suppressing activation of apoptosis-induced eIF-5A in a cell or cells of a mammalian corpus luteum comprising administering an agent to the cell or cells that is capable of inhibiting DHS catalyzed chemical reactions, wherein

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the agent is selected from the group consisting of exogenous spermidine, 1,3-Diamino-propane, 1,4-Diamino-butane (putrescine), 1,7-Diamino-heptane, and 1,8-Diamino-octane; and wherein the agent is not administered at toxic levels; and wherein the inhibiting apoptosis-induced DHS catalyzed chemical reactions inhibit or reduce an apoptosis cascade, said cascade comprising transferring a 4-aminobutyl residue from an endogenous spermidine to a  $\epsilon$ -amino group of a conserved lysine on an inactive apoptosis-induced eIF-5A, said transferring converting the lysine to a deoxyhypusine, and wherein a deoxyhypusine hydroxylase converts the deoxyhypusine to hypusine; and wherein inhibition or reduction of said apoptosis cascade reduces an amount of activated apoptosis-induced eIF-5 or inhibits activation of apoptosis-induced eIF-5A in the cell.

Claim 88 (currently amended): A method for inhibiting or delaying apoptosis in a cell or cells of a mammalian corpus luteum, comprising administering to said cell or cells an agent that is capable of inhibiting an apoptosis-induced DHS catalyzed chemical reaction, wherein the agent is spermidine, 1,3-Diamino-propane, 1,4-Diamino-butane (putrescine), 1,7-Diamino-heptane, and 1,8-Diamino-octane; and wherein the agent is not administered at toxic levels; and wherein said inhibiting apoptosis-induced DHS catalyzed chemical reaction reduces levels of activated apoptosis-induced eIF-5A or inhibits activation of apoptosis-induced eIF-5A; and wherein said reduction of apoptosis-induced eIF-5A or inhibition of activation of apoptosis-induced eIF-5A inhibits or delays apoptosis in said cell.

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Claim 89 (previously presented) A method for inhibiting or delaying apoptosis in a cell or cells of a mammalian corpus luteum, comprising administering to said cell spermidine, wherein the spermidine inhibits an apoptosis-induced DHS catalyzed chemical reaction to reduce levels of activated apoptosis-induced eIF-5A or to inhibit activation of apoptosis-induced eIF-5A; and wherein said reduction of apoptosis-induced eIF-5A or inhibition of activation of apoptosis-induced eIF-5A inhibits or delays apoptosis.

### ***Conclusion***

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

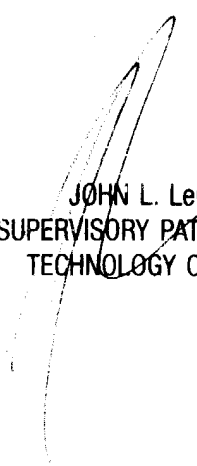
Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

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provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JD Schultz, PhD



JOHN L. LeGUYADER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600